Robot-Assisted Versus Open Radical Prostatectomy: A Contemporary Analysis Of An All-Payer Discharge Database

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RUNNING TITLE: Comparison of outcomes and costs of open versus robot-assisted prostatectomy

ABSTRACT

BACKGROUND: More than a decade since its inception, the benefits and cost-efficiency of robot-assisted radical prostatectomy (RARP) continue to elicit controversy.

OBJECTIVE: To compare outcomes and costs of RARP vs. open RP (ORP).

DESIGN, SETTING AND PARTICIPANTS: A cohort study of 629,593 men who underwent RP for localized prostate cancer at 449 hospitals in the United States from 2003 to 2013, using the Premier Hospital Database.

INTERVENTION: RARP was ascertained through a review of the hospital charge description master for robotic supplies.

OUTCOME MEASURES AND STATISTICAL ANALYSIS: 90-day postoperative complications (Clavien), blood product transfusions, operating room time, length of stay and direct hospital costs. Propensity-weighted regression analyses accounting for clustering by hospitals and survey weighting ensured nationally representative estimates.

RESULTS AND LIMITATIONS: Utilization of RARP grew rapidly from 1.8% in 2003 to 85% in 2013 (p<0.001). RARP patients (n=311,135) were less likely to experience any complications (OR 0.68, p<0.001), prolonged LOS (OR 0.28, p<0.001), or receive blood products (OR 0.33,p =0.002) compared to ORP patients (n=318,458). RARP's adjusted mean ORT was 131 min (p=0.002) longer. 90-day direct hospital costs were higher for RARP (+$4528, p<0.001), primarily attributed to operating room and supplies costs. Costs were no longer signficantly different between ORP and RARP among the highest volume surgeons (≥104 cases/year) (+$1990, p=0.40) and highest volume hospitals (≥318 cases/year) (+$1225, p=0.39) Limitations included lack of oncologic characteristics and the retrospective nature of the study.

CONCLUSIONS: Our contemporary analysis found that RARP confers a perioperative morbidity advantage at higher costs. In the absence of large randomized trials due to the widespread adoption of RARP, this retrospective study represents the best available evidence for the morbidity and cost profile of RARP vs. ORP.

PATIENT SUMMARY: In this large study of men with prostate cancer who underwent either open or robotic radical prostatectomy, we found robotic surgery had a better morbidity profile, but costs more.

INTRODUCTION

Prostate cancer is the commonest non-skin malignancy and the second leading cause of cancer death among men in the United States (US) [1]. Radical prostatectomy (RP) is an established treatment modality for localized prostate cancer [2], associated with a survival advantage compared to watchful waiting [3]. In the past decade, robot-assisted radical prostatectomy (RARP has rapidly disseminated in the US largely driven by extensive patient-directed marketing and inter-hospital competition to offer the latest technology. Despite RARP's rapid adoption, there exists no large-scale randomized controlled trial demonstrating its superiority over open RP (ORP) [4,5]. Instead, the best evidence has so far come from observational cohort studies and meta-analyses [6,7]. The latest comparative study of 5,915 Medicare patients treated with either ORP or RARP between 2008 and 2009, found no differences in complications, readmissions and additional cancer therapies, but a benefit with regard to blood transfusions and length of stay (LOS) [8]. Another National Inpatient Sample (NIS) study across the same time period included 19,462 patients of all age groups and insurance status found that RARP had decreased rates of intra- and postoperative complications [9].

In light of these inconclusive findings regarding RP's morbidity profile, we sought to re-examine the perioperative outcomes and costs of RARP compared to ORP, hypothesizing that RARP would be associated with better morbidity but higher costs.

PATIENTS AND METHODS

Data source

We analyzed data from Premier Hospital Database (Premier, Inc., Charlotte, NC), a nationally representative all-payer dataset capturing over 45 million hospital inpatient discharges, representing approximately 20% of all hospitalizations in the US. Premier's data has been validated and used in previous landmark studies [10,11]. We received institutional review board exemption for this study.

Hospital-specific projection weights are applied to each discharge to project the sample to a national estimate of inpatient discharges. Premier's projection methodology was validated by the Food and Drug Administration in 2001; it is based upon a stratified comparison of Premier's inpatient database to all US hospitals responding to the American Hospital Association Annual Survey and validated through a comparison to projections using the National Hospital Discharge Survey. Hospital-level projection weights are then applied to each discharge in the Premier database. All numbers reported herein refer to projected estimates.

Study cohort and main exposure

Using *International Classification of Diseases, Ninth Revision* (*ICD-9*) codes, we identified men diagnosed with prostate cancer (185) who underwent RP (60.5) between

2003 and 2013. Men with metastatic disease (196.x, 197.x, 198.x) and other malignancies (140.x to 209.79) were excluded. Patients who had a code for a robot-assisted procedure (*ICD-9* 17.42 or 17.44 introduced in October 2008) or a recorded charge code for robotic instrumentation were classified as RARP. These charge codes were obtained through a thorough review of the charge description master (CDM) specifically identifying supplies unique to robotic procedures, via a combination of flagging every item in the EndoWrist® Instrument and Assessory Catalog from Intuitive Surgical® and manual review, similar to the methodology described in a previous study [11]. We excluded the limited proportion of non-robotic, laparoscopic RPs (n=27,619;4.2%) in order to have a comparison between ORP and RARP only.

Covariates

We examined relevant patient, hospital, and surgical characteristics: (1) patient characteristics included age (<55, 55-64, 65-74, ≥75 years), race (White, Black, Hispanic, other/unknown), marital status (married, non-married), insurance status (Medicare, Medicaid, private, other/unknown), and CCI (0, 1, ≥2); (2) hospital characteristics included teaching status, hospital size (<400, 400-600 or >600 beds), location (urban or rural), and geographical region (Midwest, Northeast, South or West); (3) surgical characteristics included year of procedure, type of surgical approach (robotic vs. open) and annual surgeon and hospital volume. Annual surgical volume was calculated based on the annual number of RP performed, irrespective of surgical approach. In the absence of clear cut-off references [12], we defined the highest volume as ≥75th percentile (highest quartile), as other authors have done [13-15]: for surgeon volume: ≥104 cases per year, i.e. ≥2 cases per week and for hospital volume: ≥318 cases/year, i.e. nearly 1 case per day.

Endpoints

We used *ICD-9* codes to identify events defined by the Clavien classification system, including events not present at the time of the admission for RP but occurring during the index hospital stay and/or on re-admission to the hospital within 90 days of the procedure[16]. Patients with events managed in the outpatient setting were not captured. Complications were classified as any (Clavien grade 1-5) or major (Clavien grade 3-5). Clavien grade 5 denoted mortality and was identified through disposition codes., Our methodology met 7 out of the 10 Martin criteria according to European Association of Urology guidelines [17].

We utilized the CDM to determine the number of units of blood product utilized and, operating room time (ORT). ORT indicates actual ORT instead of time from incision to closure, allowing inference about operating room (resource) utilization (“wheels in, wheels out”) rather than the speed of the surgeon (e.g. robotic console time). Hospital LOS (days) was directly captured by the database, indicating the period from admission to discharge. Prolonged LOS was defined as LOS >median of 2-days.

Total expenditure associated with surgery were estimated using 90-day direct hospital costs for each patient. These consisted of the actual cost to treat the patient, including supplies, labor, depreciation of equipment etc., and included variable (direct) and fixed costs(overhead). The capital costs and annual maintenance fees associated with the robotic platform were not included; these fixed costs per case are dependent on the specific type of robotic unit as well as the amortization of these costs based on the frequency and duration of use, [18,19] none of which is reliably available in the current database. To facilitate comparison, all costs were adjusted to 2014 US dollars using the Consumer Price Index.

Statistical analyses

Using descriptive statistics, we compared baseline characteristics of ORP vs. RARP using chi-square (categorical) and Mann-Whitney (continuous) tests. For continuous outcomes (LOS, ORT and 90-day direct hospital costs), differences between ORP and RARP were found to have a gamma distribution, so we constructed generalized linear regression models. Postoperative blood tranfusions were analyzed both as categorical (yes/no) and count variables (number of units of blood products). For categorical outcomes, we performed logistic regression to estimate the odds ratios [ORs] of the outcome for RARP compared to ORP. Negative binomial regression was used for blood products (number of units) when analyzed as count variables.

To minimize selection bias, we employed propensity scores to control for potential confounders between ORP and RARP patients; these included all characteristics listed in the "*Covariates*" paragraph. Each patient was weighted by the inverse propensity of being treated by ORP or RARP [20]. The propensity of being "assigned" to either ORP or RARP was calculated using multivariable logistic regression models based on the above confounders. To account for inter-hospital variability, we adjusted for clustering of patients within hospitals [21]. There was no missing data. To examine if surgical volume or time period of surgery exerted any effect modification on the type of procedure (ORP vs. RARP), we examined the significance of interaction terms and subsequently performed subgroup analyses accordingly. Statistical analyses were performed using SAS 9.3 (SAS Institute, NC) and reported in accordance to European Urology guidelines [22]. All tests were two-sided and a p-value of <0.05 was considered statistically significant.

Threshold Analysis

Since prior studies have shown that surgical volume is inversely related to ORT [23], complications and positive surgical margins for robotic procedures [24], we performed a threshold analysis with a deterministic model using TreeAge Pro Suite 2015 (TreeAge Software, Inc., Williamstown, MA) to identify the clinical scenario achieving a cost advantage for RARP over ORP. We used inputs from our statistical models and varied the values of modificable variables (ORT, annual surgical volume, and complication rates) for RARP vs. ORP.

RESULTS

Study Cohort

The final propensity-weighted study cohort comprised of 629,593 men who underwent either ORP or RARP at 449 US hospitals. Pre- and post-propensity-weighted characteristics are summarized in **Table 1**.

Over the study period, 311,135 (49.4%) RPs were performed with robotic assistance. The proportion of RARP increased steadily across the years, from 1.8% in 2003 to 9.8% in 2004 (“Innovation Phase”), 21.8% in 2005 to 35.4% in 2007 (“Early Adopter Phase”), 47.8% in 2008 to 76.5% in 2010 (“Early Majority Phase”), and 81.0% in 2011 to 85.6% in 2013 (“Late Majority Phase”) ($p < 0.0001$) (**Figure 1**).

Perioperative Outcomes

Unadjusted outcomes are shown in **Table 2** and **Appendix Table 1**. After accounting for confounding variables, RARP was found to have a 32% decreased odds of 90-day complications (OR: 0.68, 95% confidence interval [CI]: 0.55–0.83,$p<0.001$). There were no significant difference in 90-day major complication rates (OR: 1.00, 95% CI: 0.73 to 1.38, $p=0.99$). RARP patients were also less likely to receive intra- or post-operative blood products (OR: 0.33, 95% CI: 0.19 to 0.59,$p<0.001$). RARP was associated with a longer adjusted mean ORT (+131 minutes, 95% CI: +48 to +213,$p=0.002$). The magnitude of difference between ORP and RARP was less pronounced among the highest volume surgeons (+32 minutes, 95% CI: +5 to +59, p=0.02) and hospitals (+43 minutes, 95% CI: +5 to +81, p=0.03). Analyses stratified according to time periods were performed and our results were generally consistent with the main analyses (**Table 3**).

Costs

RARP was associated with higher 90-day direct hospital costs (RARP vs. ORP: $14,897 vs. $9558, adjusted difference: +$4,528, 95% CI: $2,928 to $6,127, p<0.001), hugely driven by supplies (RARP vs. ORP: $4,267 vs. $1,089, adjusted difference: +$5,545, 95% CI: $3,904 to $7,187, p<0.001) and OR costs (RARP vs. ORP: $7,013 vs. $4,529, adjusted difference: +$3,146, 95% CI: $1,592 to $4,700, p<0.001) (**Figure 2**). The shorter mean length of stay in RARP patients (RARP vs. ORP: 1.71 vs. 2.95, adjusted difference: -0.75 days, 95% CI: -0.99 to -0.50, p<0.001) corresponded with the significant decrease in room and board costs (RARP vs. ORP: $1,885 vs. $2,264, adjusted difference: -$784, 95% CI: -$1,384 to -$181, p<0.001). Subgroup analyses showed that cost-differences between ORP and RARP were no longer significant among the highest-volume surgeons (p=0.15) and hospitals (p=0.39) (**Table 3**).

Threshold Analysis

Annual surgical volume and ORT were among the most influential factors on RARP costs while a change in the probability of any complication (Clavien ≥1) had a modest impact. With multi-way sensitivity analysis, we estimated that at an average complication rate of 9.53%, an annual surgeon volume of 20 cases/year, for RARP to cost less than ORP, the ORT taken for the entire RARP to complete would have to be ≤152 minutes. Assuming an annual hospital volume of 126 cases/year, our results remained similar; the ORT taken for RARP would have to be ≤156 minutes. The relationship of ORT with annual surgeon volume or hospital volume on 90-day direct hospital costs for ORP vs. RARP are shown in **Figures 3a and 3b,** respectively.

DISCUSSION

Our contemporary population-based study demonstrated rapid adoption of RARP between 2003 and 2013 in accordance to the Law of Diffusion of Innovation [25]. RARP was also associated with decreased morbidity compared to ORP, while incurring significantly higher costs. This current study expanded upon the findings of the latest cohort studies, which were limited to a little more than a year's data between October 2008 and December 2009 [8,9]. Our results confirmed that patients undergoing RARP experienced less overall postoperative complications, although this morbidity advantage did not extend into the major complications category.

Comparison with previous studies

In the current healthcare climate of cost-containment, examining expenditures is imperative in healthcare technology assessment. The higher costs for RARP (>$5000) compare well with single-institutional studies reporting a $4,300 loss per RARP case when considering both direct and indirect costs [26]. Another study revealed that the median direct cost was about $2000 more for RARP than ORP, with the main differences in surgical supply (RARP: $2015; ORP: $185) and operating room (RARP: $2798; ORP: $1611;p<0.001) costs [27]. This was consistent with the findings in our study, i.e. robotic surgery-specific supplies and operating room costs were the main contributors to higher costs for RARP (**Figure 2**). This may be a potential target for cost-containment initiatives, with greater commercialization and mass production. It is also important to note that our costs analyses did not include the initial fixed cost of acquiring the robot, which can cost up to $2.5 million, and ongoing maintenance and repair costs. It was estimated that when the amortized cost of the robot itself was included, the additional total cost of performing RARP (over ORP) was up to $4800 in 2007 in the US [18]. A more recent economic model in Australia found the incremental cost per RARP case compared with ORP was $1,933 for the da Vinci Si model [19].

Robotic surgery proponents assert that reduced LOS results in decreased costs; we indeed found that RARP conferred a shorter LOS than ORP, translating into room and board costs savings. Additionally, it is possible that there may be an unmeasured benefit associated with decreased convalescence and earlier return to work for RARP patients [28].

With prostate cancer being the commonest male solid organ malignancy, reducing its economic burden on the healthcare system is paramount. Our study suggests that reducing ORT and having the surgery performed by a higher volume surgeon or hospital would substantially decrease RARP costs; the development of a postoperative complication had a less pronounced impact on costs. While our analysis did not include the fixed costs associated with acquiring the robotic platform in the first place, our analysis clearly demonstrated that a marked decrease in ORT was necessary to make RARP cost-competitive with ORP. Given that surgical volume is associated with surgical efficiency [12], we speculated that high-volume surgeons were more likely to surmont the learning curve, improve procedural efficiency, and sufficiently reduce their ORT to justify the elevated costs associated with RARP. Our data also demonstrated that cost differences between ORP and RARP were no longer significantly different among the highest volume surgeons and hospitals, supporting centralization to high-volume providers, as advocated for major cancer surgery [29]. However, in the context of the United States, this may be difficult given that over 85% of RPs are already performed via the robotic approach, and robotic training has disseminated through increasing resident involvement [30,31].

This study represented the largest comparative analysis of RARP vs. ORP. By relying on CDM to identify supplies unique to robotic surgery, we provided the first true temporal trend analysis of RARP utilization in the US. Previous studies relied on ICD-9-CM or CPT procedural codes and showed a surge in minimally invasive RP in late 2008, which may have been simply attributed to the emergence of a dedicated robotic surgery procedural code. Indeed, a recent cross-analysis of NIS and Premier's data suggest that up to 39% of RARPs may be miscoded as ORPs in the NIS [32]. Our combined approach to identify RARP allowed us to provide an accurate comparison of RARP vs. ORP from the early adoption (2003-2004) to the late majority (2011-2013) periods rather than a mere snapshot of a constrained period [6,9]. Indeed, two large studies on temporal trends in the adoption and outcomes of minimally-invasive surgeries for prostatectomy have found lower postoperative complication rates for minimally-invasive procedures as compared to ORP over time [33,34]. Another notable strength of our analysis is that we reported direct 90-day hospital costs, which better represeted true resource utilization, compared to cost–to-charge ratios, as required by other datasets (e.g., NIS) [35], which may not accurately depict true costs. This is fundamental in evaluating robotic surgery's cost-efficiency.

Limitations

This study has several limitations. Firstly, our study was only based on a sampling of hospitals in the US. We employed clustered statistical analyses while accounting for survey weights [21], similar to prior population-based studies to reduce sampling bias [9,16,33]. Secondly, our secondary analysis of administrative data is subject to potential misclassification bias of postoperative complications. Consequently, the minor complication rate (Clavien 1-2) in our cohort may be underestimated. However, our results mirror those of previously reported grade 1-2 complication rates.[7] Additionally, both RARP and ORP are subject to the same bias thus permitting a valid comparison. Another limitation is that the IPTW employed to reduce selection bias may accentuate unmeasured confounders such as oncologic characteristics such as PSA and TNM stages [36], which were not available in this dataset.

Additionally, despite accounting for year of surgery, we are unable to fully account for other changes over time which may lead to differences in outcomes between ORP and RARP. For example, there have been refinements in surgical technique and approach for RARP which could also account for better outcomes [37]. More profoundly, our results do not reflect underlying quality of care initiatives that might have been implemented to improve outcomes. For example, data from universal healthcare systems have suggested that standardized care pathways have increased the efficiency of post-operative benchmark measures auch as LOS without compromising complications or readmission rates [38]. Given the large differences in our outcomes between ORP and RARP, it is quite plausible that these findings are at least partly explanined by these unmeasured confounders rather than the surgical approach alone.

Furthermore, our study's short follow-up precluded us from evaluating important long-term endpoints such urinary incontinence, erectile dysfunction and cancer-specific survival. A previous study had found higher rates of incontinence and erectile dysfunction among men who underwent minimally invasive RP compared to ORP; this may represent the early experience of RARP (data from 2003 to 2007). Nevertheless these 2 important complications need to be emphasized to all patients undergoing RARP. Additionally relying on diagnosis codes for functional outcomes do not inform severity of the condition; the same code for urinary incontinence may refer to either a patient using 1 security pad a day for stress incontinence or a severely incontinent patient who uses numerous pads a day [39]. Lastly, health-related quality of life assessment was not available for comparison; a nationwide evaluation using the Health Professionals Follow-up Study found no significant differences in health-related quality of life between ORP and RARP [40].

CONCLUSIONS

Our contemporary population-based study showed a rapid adoption of RARP between 2003 and 2013 in the US. RARP was found to have decreased morbidity compared to ORP, in particular lower 90-day postoperative complication rates, blood transfusion rates and decreased LOS, even among multimorbid patients. RARP had higher 90-day direct hospital costs, attributable to higher supplies and operating room costs. This cost difference with ORP was not apparent among the highest volume surgeons. Future updated comparative analyses using cost-effectiveness analysis may be of value by incorporating outcomes, quality of life, and costs of ORP and RARP [41].

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FIGURE LEGENDS

Figure 1. Trend Of Surgical Approach For Radical Prostatectomy In The United States From 2003 to 2013

Figure 2. Adjusted Cost Comparisons Of Open Radical Protatectomy (ORP) And Robot-Assisted Radical Prostatectomy (RARP) In The United States From 2003 To 2013, Including Costs Breakdowns

Figure 3a .The Relationship Between Operating Room Time And Annual Surgeon Volume On 90-Day Direct Hospital Costs For Open Radical Protatectomy (ORP) Versus Robot-Assisted Radical Prostatectomy (RARP) In The United States. The light grey regions indicate the parameters for which RARP will be cheaper compared to ORP

Figure 3b. The Relationship Between Operating Room Time And Annual Hospital Volume On 90-Day Direct Hospital Costs For Open Radical Protatectomy (ORP) Versus Robot-Assisted Radical Prostatectomy (RARP) In The United States. The light grey regions indicate the parameters for which RARP will be cheaper compared to ORP